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(54) GASTROINTESTINAL BIOPSY DEVICES

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(57) **ABSTRACT**

This document provides methods and materials involved in obtaining biopsy material from the gastrointestinal tract of a mammal (e.g., a human). For example, devices (e.g., percutaneous biopsy devices) configured to allow a user (e.g., a surgeon) to obtain biopsy material from the gastrointestinal tract of a mammal in a minimally-invasive manner as well as methods for using biopsy devices are provided.

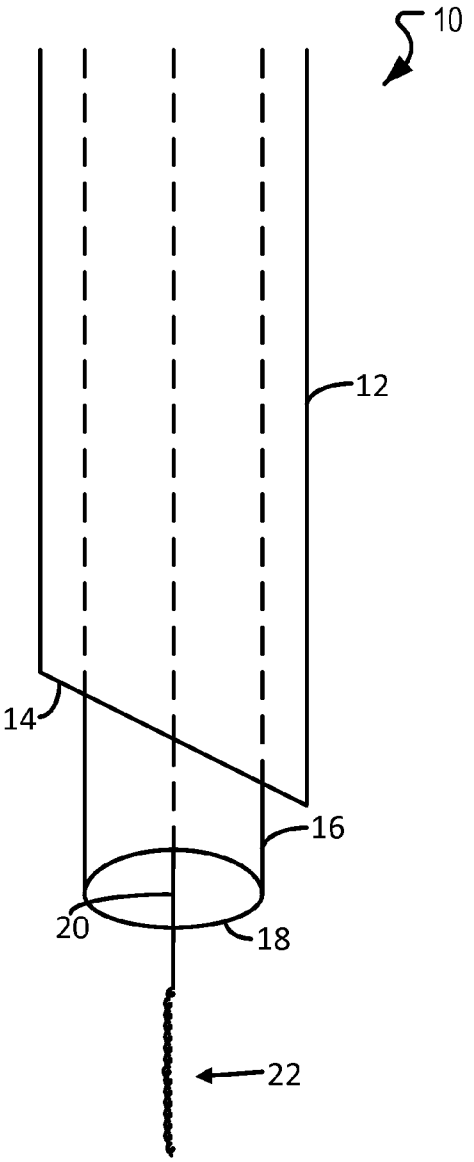


Figure 1

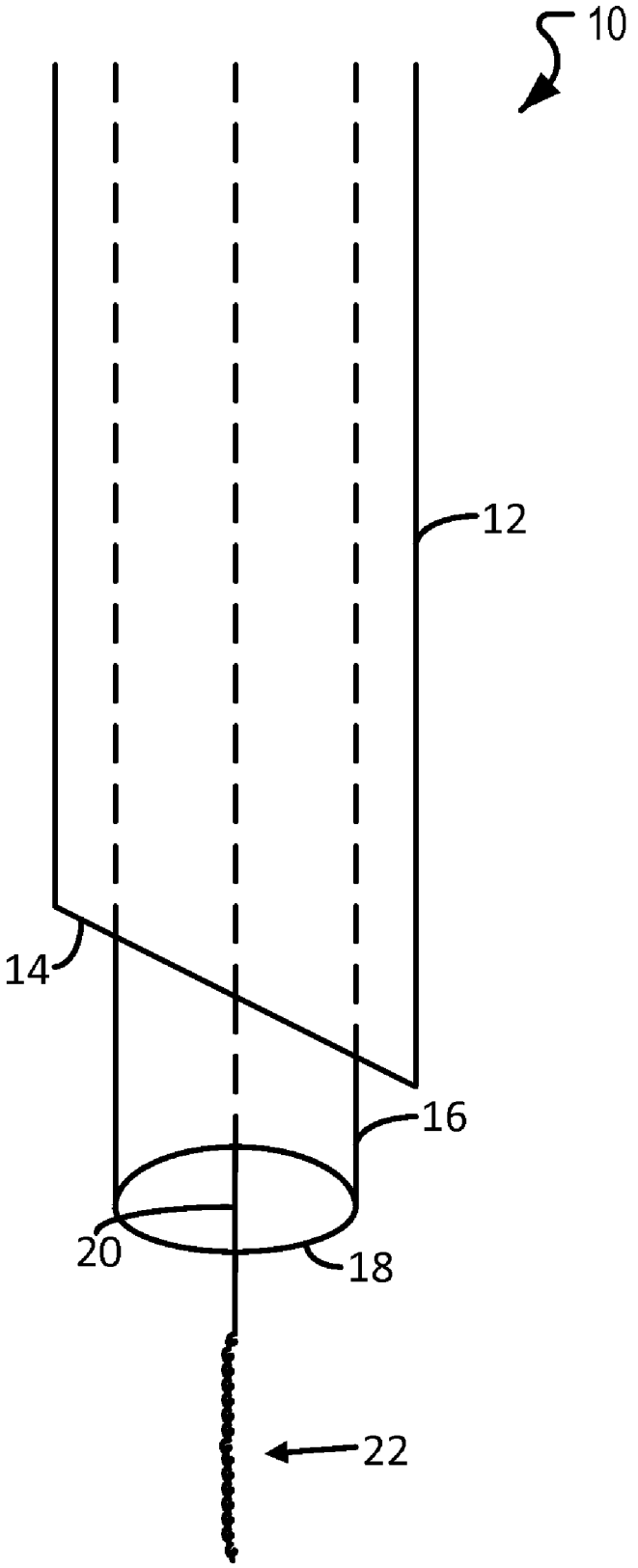


Figure 2

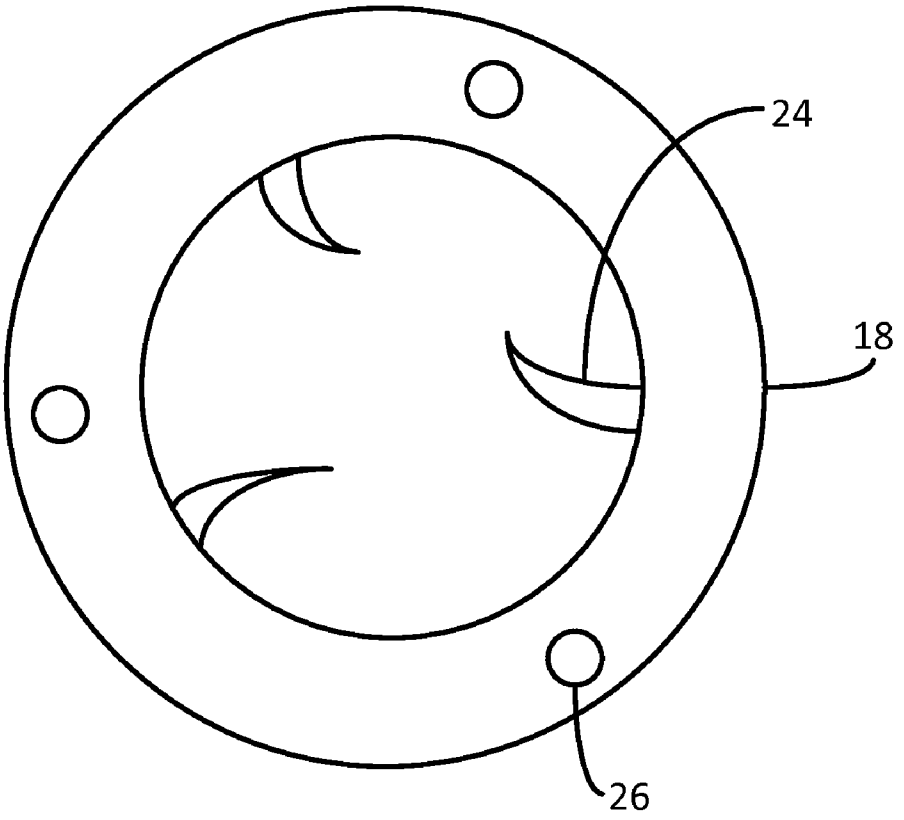


Figure 3

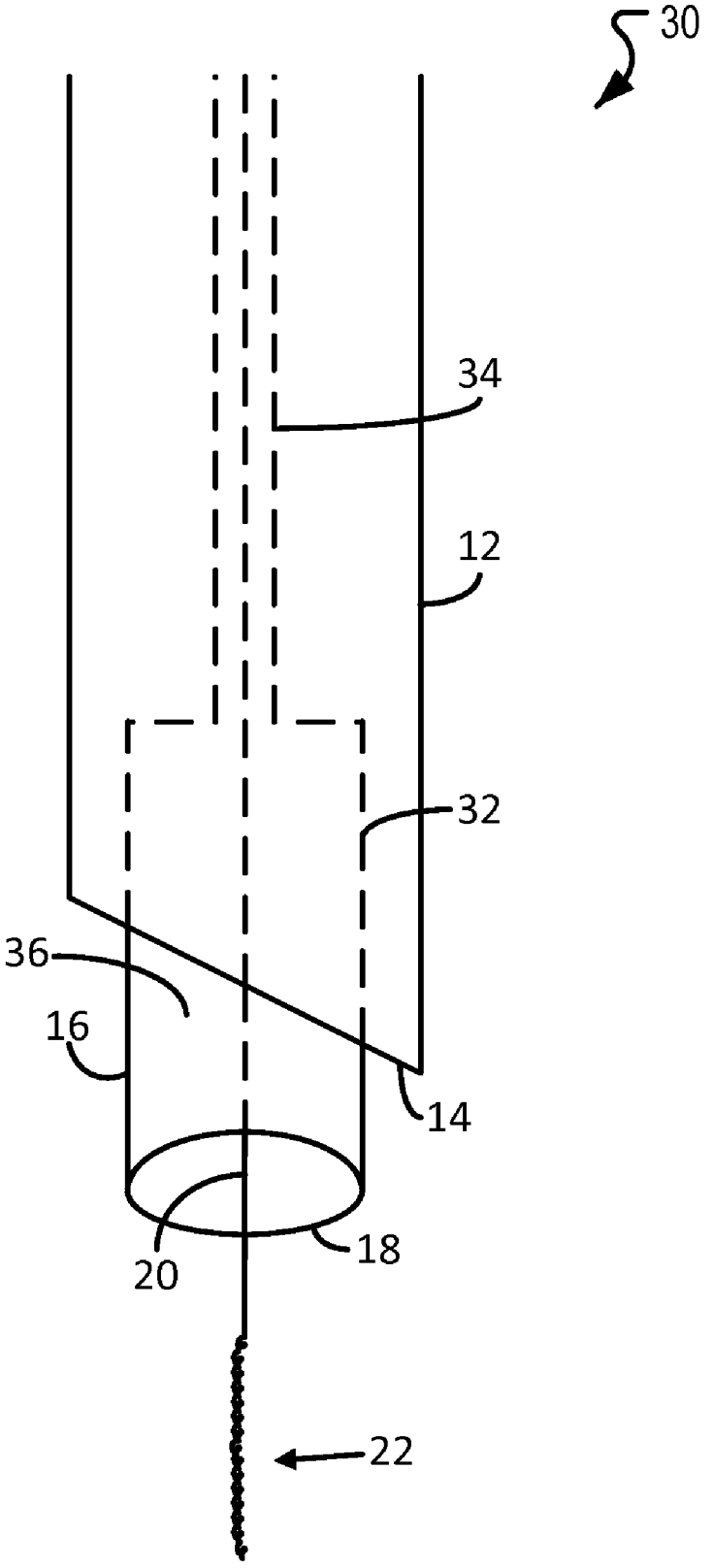


Figure 4

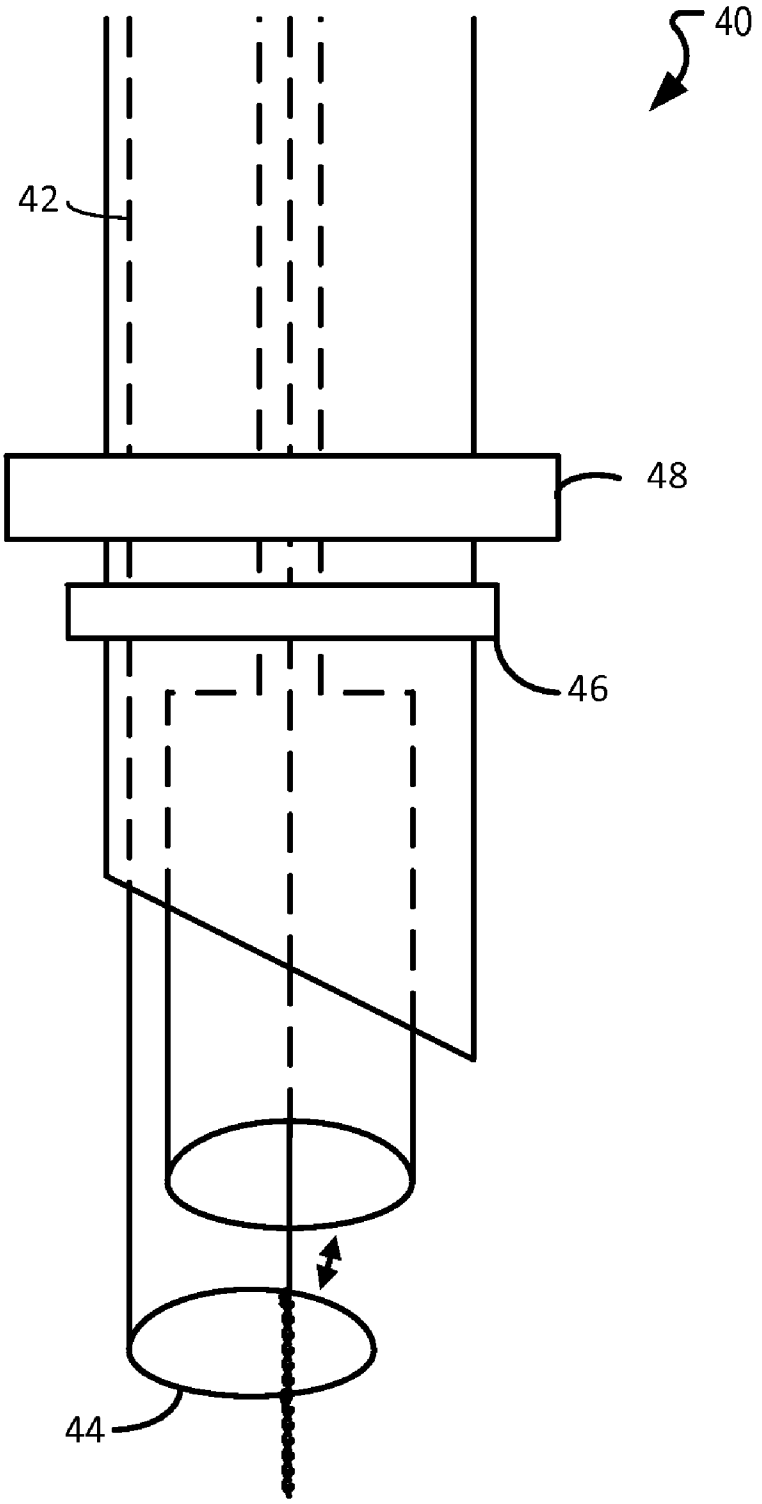


Figure 5

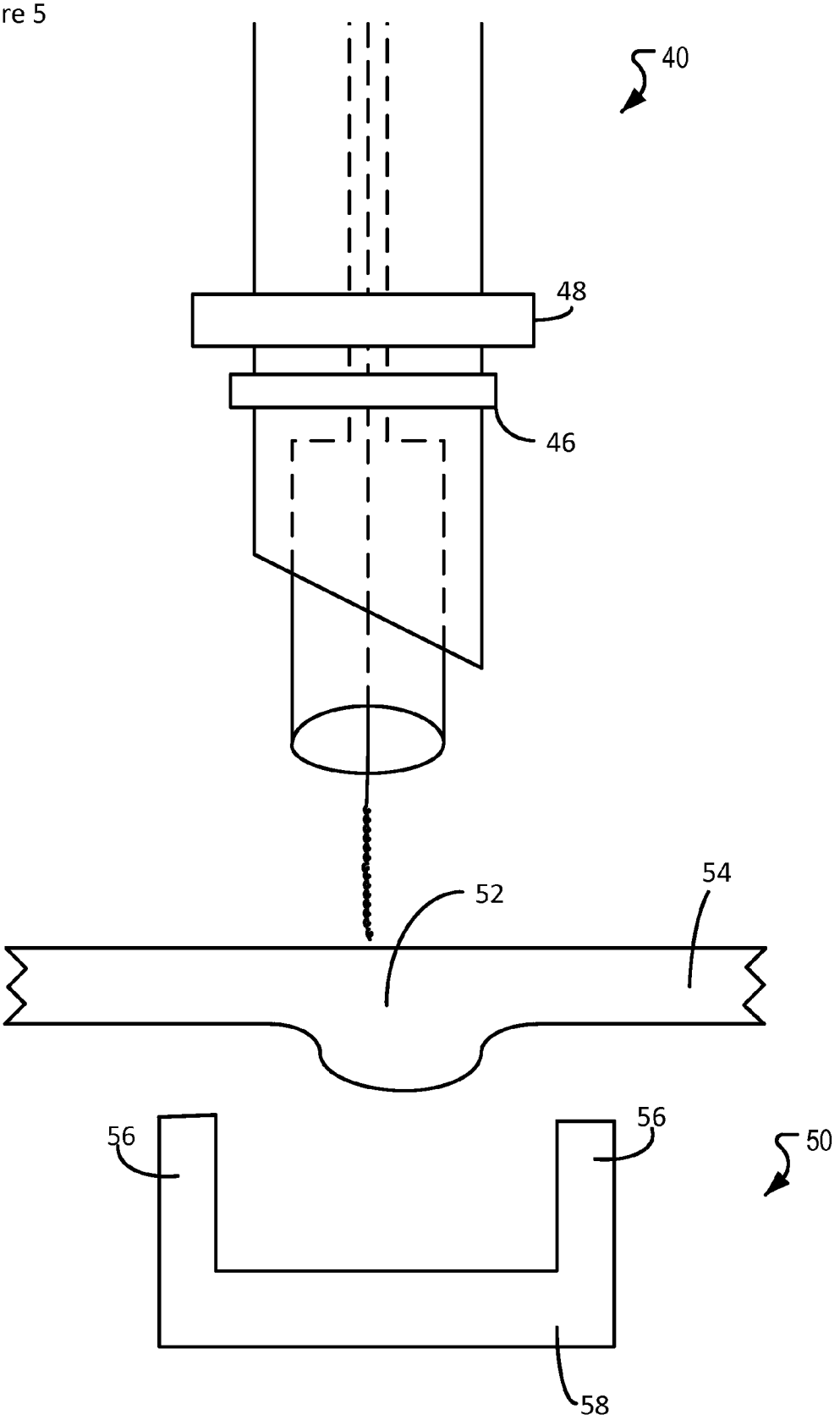


Figure 6

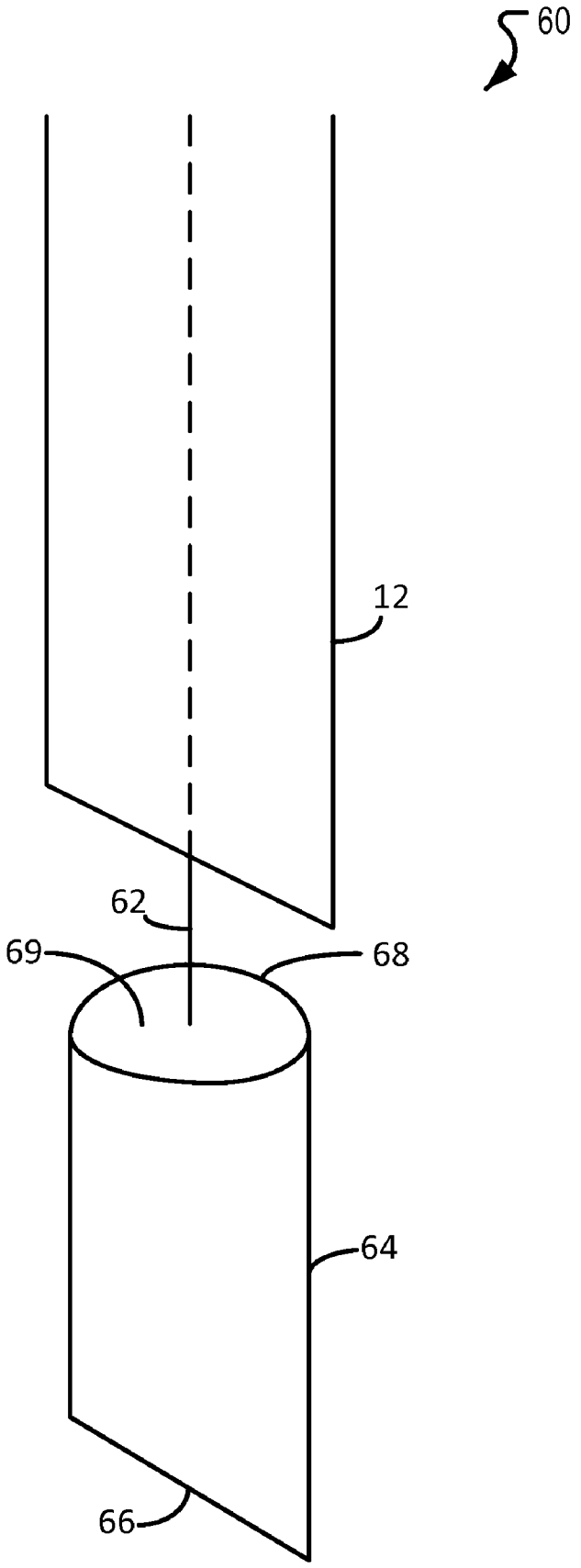
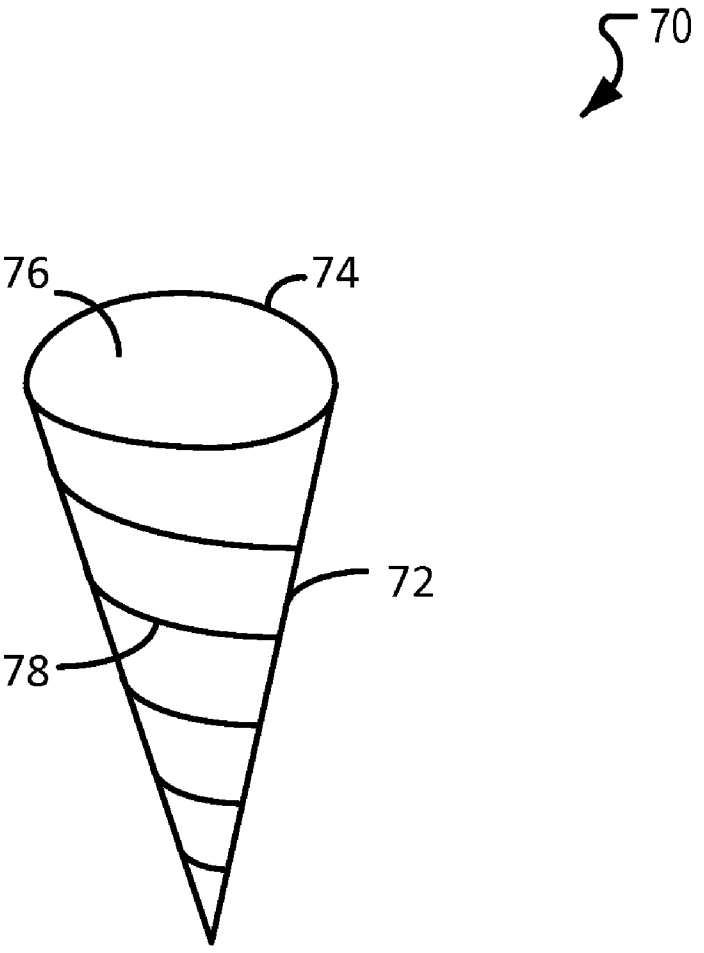


Figure 7



GASTROINTESTINAL BIOPSY DEVICES

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Application Ser. No. 61/509,027, filed Jul. 18, 2011. The disclosure of the prior application is considered part of (and is incorporated by reference in) the disclosure of this application.

BACKGROUND

[0002] 1. Technical Field

[0003] This document relates to methods and materials involved in obtaining biopsy material from the gastrointestinal tract of a mammal (e.g., a human). For example, this document relates to devices (e.g., percutaneous biopsy devices) configured to allow a user (e.g., a surgeon) to obtain biopsy material from the gastrointestinal tract of a mammal in a minimally-invasive manner.

[0004] 2. Background Information

[0005] Tissue samples are routinely removed from a living mammal to determine the presence or extent of a disease. In such cases, the tissue biopsy is typically examined under a microscope by a pathologist. There are several different types of biopsy procedures. For example, when an entire lump or suspicious area is removed, the procedure can be called an excisional biopsy. When a sample of tissue is removed with preservation of the histological architecture of the tissue's cells, the procedure can be called an incisional biopsy or core biopsy. When a sample of tissue or fluid is removed with a needle in such a way that cells are removed without preserving the histological architecture of the tissue cells, the procedure can be called a needle aspiration biopsy.

SUMMARY

[0006] This document provides methods and materials involved in obtaining biopsy material from the gastrointestinal tract of a mammal (e.g., a human). For example, this document provides devices (e.g., percutaneous biopsy devices) configured to allow a user (e.g., a surgeon) to obtain biopsy material from the gastrointestinal tract of a mammal in a minimally-invasive manner as well as methods for using biopsy devices. In some cases, the methods and materials provided herein can be used in a medical setting to allow a surgeon to acquire large pieces of gastrointestinal tract tissue (e.g., stomach, small bowel, or colon tissue) safely. In some cases, the methods and materials provided herein can be used to obtain large core diameter samples of a particular selected depth (e.g., a depth selected to obtain desired tissue or tissue having a desired cell type). For example, the methods and materials provided herein can be used to obtain core samples having a depth such that the core includes serosa, muscle, submucosa, and/or mucosa. In some cases, the methods and materials provided herein can be used to obtain a tissue sample having enteric nerves, interstitial cells of Cajal (ICC), and/or immune cells. Having the ability to obtain desired tissue samples as described herein can allow pathologists to determine the presence or extent of a disease quickly and effectively.

[0007] In general, one aspect of this document features a system for obtaining a tissue biopsy from the gastrointestinal tract of a mammal. The system comprises, or consists essentially of, (a) a hollow member configured to be positioned near gastrointestinal tissue to be obtained, (b) a tissue collection element configured to be advanced within a lumen of the hollow member, wherein the tissue collection element defines a lumen configured to house at least a portion of the tissue biopsy, and (c) a positioning element configured to be advanced within the lumen of the tissue collection element or the lumen of the hollow member, wherein the positioning element is capable of being advanced into gastrointestinal tract tissue and capable of positioning the gastrointestinal tract tissue into the lumen of the tissue collection element upon retraction of the positioning element. The mammal can be a human. The hollow member can be a flexible catheter or a rigid catheter. The gastrointestinal tract tissue can be a polyp. The gastrointestinal tract tissue can be normal or abnormal. The tissue collection element can comprise one or more blades. The tissue collection element can define one or more ports configured to deliver material from outside of the body of the mammal to the gastrointestinal tract of the mammal. The hollow member can comprise a bumper element. The hollow member can comprise a magnetic alignment element. The system can comprise a snare. The positioning element can comprise a screw-like structure.

[0008] In another aspect, this document features a method for obtaining a tissue biopsy from a gastrointestinal tract of a mammal. The method comprises, or consists essentially of: (a) inserting a member having a distal end and a proximal end into the mammal to position the distal end of the member proximal to tissue of the gastrointestinal tract, wherein the member defines a lumen, (b) positioning a tissue collector element within the lumen of the member, wherein the tissue collector element defines a lumen configured to house the tissue biopsy, (c) advancing a positioning element having a distal end and a proximal end within the lumen of the member or the lumen of the tissue collector element, (d) inserting the positioning element into tissue of the gastrointestinal tract, (e) advancing the tissue collector element into the tissue of the gastrointestinal tract, retracting the positioning element, or both, wherein the tissue is positioned within the lumen of the tissue collector element, and (f) separating tissue positioned within the lumen of the tissue collector element from other tissue of the mammal, thereby obtaining the tissue biopsy. Step (f) can comprise using a cutting element to separate tissue positioned within the lumen of the tissue collector element from other tissue of the mammal, thereby obtaining the tissue biopsy. Step (f) can comprise using a snare element to separate tissue positioned within the lumen of the tissue collector element from other tissue of the mammal, thereby obtaining the tissue biopsy. The method can comprise removing the tissue collector element from the mammal. Unless otherwise defined, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention pertains. Although methods and materials similar or equivalent to those described herein can be used to practice the invention, suitable methods and materials are described below. All publications, patent applications, patents, and other references mentioned herein are incorporated by reference in their entirety. In case of conflict, the present specification, including definitions, will control. In addition, the materials, methods, and examples are illustrative only and not intended to be limiting.

[0009] The details of one or more embodiments of the invention are set forth in the accompanying drawings and the

description below. Other features, objects, and advantages of the invention will be apparent from the description and drawings, and from the claims.

DESCRIPTION OF THE DRAWINGS

[0010] FIG. **1** is a side view of an exemplary device for obtaining biopsy material from the gastrointestinal tract of a mammal.

[0011] FIG. **2** is a view of the distal end region of a tissue collector of the device of FIG. **1**.

[0012] FIG. **3** is a side view of an exemplary device for obtaining biopsy material from the gastrointestinal tract of a mammal.

[0013] FIG. **4** is a side view of an exemplary device for obtaining biopsy material from the gastrointestinal tract of a mammal.

[0014] FIG. **5** is a side view of an exemplary device for obtaining biopsy material from the gastrointestinal tract of a mammal together with mammalian gastrointestinal tissue.

[0015] FIG. **6** is a side view of an exemplary device for obtaining biopsy material from the gastrointestinal tract of a mammal.

[0016] FIG. **7** is a side view of one example of a tissue collector.

DETAILED DESCRIPTION

[0017] This document provides methods and materials involved in obtaining biopsy material from the gastrointestinal tract of a mammal (e.g., a human). For example, this document provides devices (e.g., percutaneous biopsy devices) configured to allow a user (e.g., a surgeon) to obtain biopsy material from the gastrointestinal tract of a mammal in a minimally-invasive manner as well as methods for using biopsy devices.

[0018] In general, an outer hollow member (e.g., a catheter, needle, cannula, or tubular member) can be configured such that it can be advanced within a mammal's body to a position such that a gastrointestinal tissue sample can be obtained. In some cases, the outer hollow member can be the outer most component of a biopsy system described herein, or it can be housed completely or at least partially within another component (e.g., a sleeve or sheath). An outer hollow member can be any appropriate shape. For example an outer hollow member can have a non-round shape (e.g., an outer cross-sectional). In some cases, the lumen defined by an outer hollow member can have a non-round shape. For example, an inner surface of an outer hollow member can have a non-round cross-sectional shape (e.g., a circular shape with one or more straight or substantially straight edges).

[0019] In some cases, the outer hollow member can be configured to receive an inner tissue collector element. The inner tissue collector element can include a lumen configured to house a desired gastrointestinal tissue sample that was extracted from the gastrointestinal tract of a mammal. In some cases, an inner tissue collector element can include an extraction mechanism that can be used to remove a desired gastrointestinal tissue sample from the gastrointestinal tract of a mammal. Such an extraction mechanism can be one or more cutting blades. In some cases, a positioning element can be used to hold gastrointestinal tissue in place while a tissue collector element is advanced into the tissue during a tissue removal process. For example, a screw-like positioning element can be anchored into gastrointestinal tissue in the region where a gastrointestinal tissue sample is to be removed. Then, a tissue collector element having a distally located extraction mechanism (e.g., blades) can be inserted into the tissue in a manner such that the positioning element provides an appropriate degree of leverage for the tissue collector to advance a desired depth into the tissue. Once advanced the desired depth, the extraction mechanism can be used to free the desired gastrointestinal tissue to a point such that the tissue remains within a lumen of the tissue collector element as the tissue collector element is withdrawn from the mammal. In some cases, a system provided herein can include a clip or adhesive configured to close an opening created by the removal of the gastrointestinal tissue.

[0020] The methods and materials provided herein can be used to obtain any appropriate type of gastrointestinal tract tissue such as stomach, small bowel, and/or colon tissue. In some cases, the methods and materials provided herein can be used to obtain core samples having a diameter between about 1 mm and 10 mm (e.g., between about 2.5 mm and 10 mm, between about 5 mm and 10 mm, between about 1 mm and 7.5 mm, between about 1 mm and 5 mm, between about 2.5 mm and 7.5 mm, between about 2 mm and 6 mm, or between about 3 mm and 5 mm). In some cases, the size of the sample can be limited by the acceptable size of the wound on the abdomen and/or size of the hole in the gastrointestinal tract tissues. In some cases, the methods and materials provided herein can be used to obtain a sample of a particular selected depth (e.g., a depth selected to obtain desired tissue or tissue having a desired cell type). For example, the methods and materials provided herein can be used to obtain core samples having a depth such that the core includes serosa, muscle, submucosa, and/or mucosa. In some cases, the methods and materials provided herein can be used to obtain a tissue sample having enteric nerves, interstitial cells of Cajal (ICC), and/or immune cells.

[0021] The methods and materials provided herein can be used with or without ultrasound guidance. In some cases, the methods and materials provided herein can be used with or without endoscope illumination. For example, a system provided herein can be designed to include fiber optics. In some cases, a device or system provided herein can include one or more optical fibers. Such optical fiber can be used to determine which layer of tissue is being penetrated. For example, each tissue layer (e.g., fat, serosa, or submucosa) can be displayed as a different reflectivity that can be determined by intensity or color. The optical fibers can be used to incorporate a mechanism for conducting light from a distal tip region of a device back outside the body to a detector system capable of determining intensity changes and/or color changes. If selected monochromatic or filtered light of specified wavelengths are transmitted into the body, the reflectivity of the various components or structures of tissue can be absorbed or reflected in characteristic ways. These changes can be used to indicate when a layer or structure is initially touched, to detect contraction, and to detect movement through a layer(s).

[0022] In some cases, one or more optical fibers can be used to aid in navigation to determine when the device is positioned at the top of the layer of interest, when the layer of interest is penetrated, and/or when the segment of tissue should be removed. In some cases, an optical fiber can be penetrated into the desired tissue, in advance of a cutting tip, to determine the depth of a cut to be made. In some cases, an optical system can be used to detect blood, clear fluid such as saline, or other matter that would be found during the proce-

dure. In some cases, sophisticated optical techniques such as optical coherence tomography can be used in combination with the methods and material provided herein.

[0023] With respect to FIG. **1**, device **10** can include an outer hollow member **12**, a tissue collector element **16**, and a positioning element **20**. Outer hollow member **12** can have any appropriate diameter. For example, outer hollow member **12** can have a diameter capable of forming a slip fit with tissue collector element **16**. In some cases, outer hollow member **12** can have an inner diameter between about 1 mm and about 15 mm (e.g., about 5 mm), and outer hollow member **12** can have an outer diameter between about 2 mm and about 15 mm (e.g., about 6 mm). Outer hollow member **12** can have a distal end region **14**. Distal end region **14** can be pointed, sharp, curved, rounded, or blunt. In some cases, distal end region **14** can be rounded to reduce the unintentional puncturing of tissue while the outer hollow member **12** is being advanced into position within a mammal. Outer hollow member **12** can define a lumen configured to allow tissue collector element **16** to slide independently within outer hollow **12** and/or to be advance from outer hollow member **12**. Tissue collector element **16** can define a lumen and can have a distal end region **18**. The lumen of tissue collector element **16** can be any appropriate length. In some cases, the lumen can have the same inner diameter for the entire length of the lumen as shown in FIG. **1**. In some cases, tissue collector element **16** can define a lumen that is larger at the distal end than at the proximal end. For example, as shown in FIG. **3**, tissue collector element **16** can define a large lumen section **32** and a narrow lumen section **34**. In some cases, the length of large lumen section **32** can be designed to match the depth of the tissue sample to be collected.

[0024] Distal end region **18** of tissue collector element **16** can be pointed, sharp, curved, rounded, or blunt. In some cases, distal end region **18** can be sharp so that desired tissue can be removed from a mammal as tissue collector element **16** is advanced into the tissue. The lumen of distal end region **18** can be configured to house a tissue sample that is removed from a mammal.

[0025] Positioning element **20** can be configured to advance independently from within outer hollow member **12** or tissue collector element **16**. For example, as shown in FIG. **1**, positioning element **20** can be configured to advance past distal end region **18**. Positioning element **20** can be configured to advance any appropriate distance past distal end region **18**, depending on the proximity of distal end region **18** to the gastrointestinal tract. In some cases, the distance positioning element **20** advanced past distal end region **18** can be used to define the depth of the tissue sample to be collected. In some cases, a handle device for positioning element **20** can include position indicators to aid in determining the distance positioning element **20** is advanced beyond distal end region **18**. Positioning element **20** can include a distal end region **22**. In some cases, distal end region **22** can be configured to advance into tissue to be removed. For example, distal end region **22** can have a screw-like or cork screw-like configuration that is capable of providing an appropriate degree of leverage for tissue collector element **16** to advance a desired depth into tissue to be removed. In some cases, a positioning element can be configured to be a suction device or a grasping forceps-like device. In some cases, positioning element **20** can contain optical fibers to determine the layer of tissue penetrated as described herein.

[0026] Tissue collector element **16** can be configured to have the ability to remove a tissue sample for the gastrointestinal tract of a mammal. For example, distal end region **18** of tissue collector element **16** can be sharp enough to remove a tissue sample. In some cases, tissue collector element **16** can include blades. As shown in FIG. **2**, distal end region **18** of tissue collector element **16** can include blades **24** configured to cut a tissue sample from the gastrointestinal tract of a mammal. In some cases, distal end region **18** of tissue collector element **16** can include a static blade, a rotary blade (e.g., a blade capable of being turned manually or electrically), or a snare. For example, as shown in FIG. **4**, distal end region **18** of tissue collector element **16** can include a snare element **42**. Snare element **42** can have a proximal portion that extends within outer hollow member **12** or tissue collector element **16** and a distal portion **44**. Distal portion **44** can be for a loop. In some cases, such a loop can be configured to be positioned along the distal most edge of distal end region **18** of tissue collector element **16** as shown by the arrows of FIG. **4**. Such a loop can be configured to allow tissue to advance into the lumen of tissue collector element **16**. Once the desired about of tissue is advanced into the lumen, snare element **42** can be actuated such that the loop frees the desired tissue to a point such that the tissue remains within the lumen of tissue collector element **16** as it is withdrawn from a mammal (e.g., a human).

[0027] Tissue collector element **16** can be configured to have one or more ports. As shown in FIG. **2**, distal end region **18** of tissue collector element **16** can include ports **26**. Ports **26** can be configured to allow for the delivery of substances to the location of tissue removal. For example, a sealant or adhesive material can be delivered to the opening created after tissue is removed to aid in healing.

[0028] In some cases, an outer hollow member or tissue collector element can include a bumper element configured to limit the advancement of the outer hollow member or tissue collector element into tissue. For example, as shown in FIG. **4**, outer hollow member **12** can include a bumper element **46**. Bumper element **46** can be a ring structure that protrudes from an outer surface of outer hollow member **12**. Bumper element **46** can be a rubber-type element.

[0029] In some cases, an outer hollow member or tissue collector element can include a magnetic alignment element configured to align the outer hollow member or tissue collector element with a separate magnetic device. For example, as shown in FIG. **4**, outer hollow member **12** can include a magnetic alignment element **48**. Magnetic alignment element **48** can be a ring structure that protrudes from an outer surface of outer hollow member **12**. Magnetic alignment element **48** can be made of magnetic material. As shown in FIG. **5**, magnetic alignment element **48** can be used to align outer hollow member **12** with a separate magnetic device **50**. Magnetic device **50** can include a base **58** and one or more extensions **56**. Extensions **56** can be capable of magnetically associating with magnetic alignment element **48**. Magnetic device **50** can be positioned in a desired location. For example, magnetic device **50** can be position to align magnetic alignment element **48** to a submucosal cushion or bleb **52** of a gastric wall **54**.

[0030] In some cases, a system, outer hollow member, or tissue collector element provided herein can include a cautery element or have energy delivery capabilities. In some cases, sealants, hemostatic agents, sponge material, and/or foam material can be delivered via a lumen integral to outer hollow

member or a tissue collection element. For example, gel foam, a biocompatible sponge, or a foam material such as Biomerix can be used to close or plug a created opening. In some cases, a system, outer hollow member, or tissue collector element provided herein can include a clip or other device having the ability to close an opening created in a gastric wall.

[0031] With reference to FIG. **6**, device **60** can include an outer hollow member **12** and a tissue collector element **64**. Outer hollow member **12** can be configured as described herein. Tissue collector element **64** can define a lumen **69** and can have a distal end region **66** and a proximal end region **68**. Lumen **69** can be any appropriate length. Distal end region **66** of tissue collector element **64** can be pointed, sharp, curved, rounded, or blunt. In some cases, distal end region **66** can be sharp so that tissue collector element **64** can be advanced into desired tissue to be removed from a mammal. Proximal end region **68** can be sharp such that removal of tissue collector element **64** from tissue after being inserted results in the collection of a desired tissue sample. In some cases, proximal end region **68** can include one or more blades or other cutting elements. In some cases, tissue collector element **64** can be collapsible or expandable. For example, tissue collector element **64** can be advanced into a desired tissue in a collapsed configuration. Then, tissue collector element **64** can be converted into an expanded configuration and withdraw from the desired tissue. As tissue collector element **64** is withdrawn, a sharp edge of proximal end region **68** can cut a tissue sample free from the mammal's gastrointestinal tract. Tissue collector element **64** can have any appropriate shape. For example, as shown in FIG. **7**, a tissue collector element **70** can have a cone shape. In this example, tissue collector element **70** can define lumen **76** and have an outer surface **72**. Outer surface **72** can include threads **78**. Threads **78** can be used to aid the insertion of tissue collector element **70** into desired tissue.

[0032] During use, an outer hollow member of a system or device provided herein (e.g., device **10**) can be introduced percutaneously into a mammal (e.g., an abdominal cavity of a human). In some cases, peroral endoscopic or percutaneous methods (e.g., endoluminal methods) can be used to create a submucosal cushion prior to inserting an outer hollow member into the mammal. A tissue collector element can be introduced into the mammal by advancing the tissue collector element within the outer hollow member. Then, a positioning element can be introduced into the mammal by advancing the positioning element within the outer hollow member or the tissue collector element. The positioning element can be advanced further into tissue to be removed. At this point, the tissue collector element can be advanced into the tissue and/or the positioning element can be retracted such that the desired tissue is contained within the lumen of the tissue collector element. A cutting element or snare can be engaged to cut the desired tissue from the mammal's gastrointestinal tract. The tissue collector element containing the removed tissue can be removed as can the positioning element. A cautery, sealant, hemostatic, clip, or other appropriate agent or device can be applied to the opening to aid in its closure.

OTHER EMBODIMENTS

[0033] It is to be understood that while the invention has been described in conjunction with the detailed description thereof, the foregoing description is intended to illustrate and not limit the scope of the invention, which is defined by the scope of the appended claims. Other aspects, advantages, and modifications are within the scope of the following claims.

What is claimed is:

1. A system for obtaining a tissue biopsy from a gastrointestinal tract of a mammal, wherein said system comprises:

(a) a hollow member configured to be positioned near gastrointestinal tissue to be obtained,

(b) a tissue collection element configured to be advanced within a lumen of said hollow member, wherein said tissue collection element defines a lumen configured to house at least a portion of said tissue biopsy, and

(c) a positioning element configured to be advanced within said lumen of said tissue collection element or said lumen of said hollow member, wherein said positioning element is capable of being advanced into gastrointestinal tract tissue and capable of positioning said gastrointestinal tract tissue into said lumen of said tissue collection element upon retraction of said positioning element.

2. The system of claim **1**, wherein said mammal is a human.

3. The system of claim **1**, wherein said hollow member is a flexible catheter.

4. The system of claim **1**, wherein said gastrointestinal tract tissue is a polyp.

5. The system of claim **1**, wherein said tissue collection element comprises one or more blades.

6. The system of claim **5**, wherein said tissue collection element defines one or more ports configured to deliver material from outside of the body of said mammal to the gastrointestinal tract of said mammal.

7. The system of claim **1**, wherein said hollow member comprises a bumper element.

8. The system of claim **1**, wherein said hollow member comprises a magnetic alignment element.

9. The system of claim **1**, wherein said system comprises a snare.

10. The system of claim **1**, wherein said positioning element comprises a screw-like structure.

11. A method for obtaining a tissue biopsy from a gastrointestinal tract of a mammal, wherein said method comprises:

(a) inserting a member having a distal end and a proximal end into said mammal to position said distal end of said member proximal to tissue of said gastrointestinal tract, wherein said member defines a lumen,

(b) positioning a tissue collector element within said lumen of said member, wherein said tissue collector element defines a lumen configured to house said tissue biopsy,

(c) advancing a positioning element having a distal end and a proximal end within said lumen of said member or said lumen of said tissue collector element,

(d) inserting said positioning element into tissue of said gastrointestinal tract,

(e) advancing said tissue collector element into said tissue of said gastrointestinal tract, retracting said positioning element, or both, wherein said tissue is positioned within said lumen of said tissue collector element, and

(f) separating tissue positioned within said lumen of said tissue collector element from other tissue of said mammal, thereby obtaining said tissue biopsy.

12. The method of claim **11**, wherein said step (f) comprises using a cutting element to separate tissue positioned within said lumen of said tissue collector element from other tissue of said mammal, thereby obtaining said tissue biopsy.

13. The method of claim **11**, wherein said step (f) comprises using a snare element to separate tissue positioned within said lumen of said tissue collector element from other tissue of said mammal, thereby obtaining said tissue biopsy.

14. The method of claim **11**, wherein said method comprises removing said tissue collector element from said mammal.

* * * * *